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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,844	03/04/2004	Peter G. Zaphiropoulos	2921-0145P	5375
2292 7590 05/30/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER SANG, HONG				
ART UNIT 1643		PAPER NUMBER		
NOTIFICATION DATE 05/30/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Office Action Summary****Application No.**

10/791,844

**Applicant(s)**

ZAPHIROPOULOS ET AL.

**Examiner**

HONG SANG

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) 6-12 and 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

**RE: Zaphiropoulos et al.**

1. Applicant's response filed on 2/29/2008 is acknowledged. Claims 1, and 5-18 are pending. Claims 2-4 have been cancelled. Claims 6-12 and 14-18 have been withdrawn from consideration.
2. Claims 1, 5 and 13 are under examination.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 101 & 35 USC § 112, 1<sup>st</sup> paragraph***

3. The rejection of claims 1, 5 and 13 under 35 U.S.C.101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility is maintained.

The response states that the specification discloses and provides the evidence that points to an activity of the claimed PTCH2 protein, for example, by showing a strong positive signal for PTCH2 mRNA exclusively in the tumor cells of all tested basal cell carcinomas (BCCs). The response states that there is an asserted utility of the involvement of the claimed PTCH2 protein into the PTCH/SHH pathway, for example, during carcinogenesis, such as BCC. The claimed PTCH2 protein is a candidate for a tumor suppressor gene in chromosome 1p32-35 and may be used in diagnostic methods. The response states that the techniques related to gene/protein expression are well-known in the art.

Applicants' arguments have been carefully considered but are not persuasive. As indicated in the previous office action, the specification does not disclose a function or activity of the claimed PTCH2 protein. While the specification discloses that PTCH2 mRNA expression is upregulated in BCCs, there is no indication that the PTCH2 protein is overexpressed in BCCs and is useful for diagnosis or treatment of BCCs. The exact function and how the PTCH2 protein is involved in the PTCH/SHH signaling pathway were not clear at the time of the filing of the instant application. As such the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Because of these reasons, the rejection is proper and maintained.

4. The rejection of claims 1, 5 and 13 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained.

The rejection is maintained for the same reasons set forth above (see paragraph 3).

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

5. The rejection of claims 1, 5 and 13 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

The response states that the specification is enabling for the same reasons of record in the previous response. The response states that the present invention is a pioneering work that provides a basis for further scientific development.

Applicants' arguments have been carefully considered but are not persuasive for the reasons of record. As indicated in the previous office action, in the absence of a correlation between the claimed proteins and any diseases, such as cancer, the information obtained from over expression of the mRNA of PTCH2 in BCC only serves as the basis for further research on the observation itself. Therefore, absent evidence of the protein's expression including a correlation to any diseased state, one of skill in the art would not be able to predictably use the claimed proteins for diagnosing or treating any diseases including BCCs without undue experimentation.

### ***Conclusion***

6. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/  
Examiner, Art Unit 1643  
5/19/2006

/Christopher H Yaen/  
Primary Examiner, Art Unit 1643